

### III. REMARKS

The amendments submitted herein should be understood to be made as a practicality only, and should not to be construed as creating any situation of file wrapper estoppel or the like as all rights are expressly reserved and may be pursued in this or other applications, such as divisionals, continuations, or continuations-in-part if desired. Relatedly, it should be understood that the amendments made herein are made for tangential issues of clarity and as a matter of the Office's convenience or expedience only. The amendments should not be interpreted as an action that in any way surrenders a particular equivalency, surrenders any right to patent coverage, or otherwise limits any rights which the Applicant may now or hereafter assert. It should be understood that, unless and to the extent deemed broadened by this amendment, and even as amended, the Applicant expressly reserves all rights, including but not limited to: all rights to maintain the scope of literal coverage with respect to any element as may have existed under the language previously presented, all rights to maintain the scope of equivalency coverage as may have existed under the language previously presented, and all rights to re-present the prior language at any time in this or any subsequent application. To the extent currently foreseeable, no change or reduction in direct or equivalency coverage is believed to exist, and no change or reduction in direct or equivalency coverage is intended through the presentation of this amendment.

#### 35 U.S.C. § 112 Concerns

The action expressed concerns to the claims under 35 U.S.C. § 112 First and Second Paragraphs. Claim 38 references the aspect of at least 5 million per milliliter of extender to at least about 10 million per milliliter of extender. As previously stated, this aspect and one or more of these specific values are mentioned in the specification at page 19, beginning at line 16; at page 20, beginning at line 11; at page 21, beginning at line 7; at page 22, beginning at line 8; at page 22, beginning at line 18; and at page 23, beginning at line 1. Of particular note and as discussed in the interview on February 17, 2005, the values and results shown in Table 1 on page 21 and to some degree in Table 2 on page 19 highlight how the claimed ranges show significance in the data. Specifically referencing table 1, it can be seen how the results increase to a more

consistent value when the dilution is established at values of at least about 5 million per milliliter of extender to at least about 10 million per milliliter of extender. Accordingly, support for the claimed ranges is found in the specification as one skilled in the art can appreciate. The reference to 5 million per milliliter and 10 million per milliliter of extender relates to the concentration of sperm in an extender as discussed in the specification.

Claim 38 also references the aspect of cooling sex-selected sperm cells. Sperm cells can be cooled under suitable conditions within the level of skill in the art. As a non-limiting example, sperm can be cooled to 5 degrees Celsius. Of course, other temperatures may be used as one skilled in the art can appreciate.

The Applicant amends claim 43 to correct a typographical error. Claim 43 references the aspect of utilizing between about 1,000,000 and about 25,000,000 equine sperm. As previously stated, various dosages and amounts are discussed in the specification. The volume of the straws used for insemination is also mentioned as both 0.25 ml and 0.50 ml at page 17 beginning on line 30 among other locations. Applying the extension mentioned in the specification at page 11 beginning at line 26 and at page 22 beginning at line 8 with these volumes of straws, it can be understood that sperm dosages of 1,250,000 ( $2.5 \times 10^6$ /ml in a 0.50 ml straw) and 25,000,000 ( $50 \times 10^6$ /ml in a 0.50 ml straw) were used. Further, at page 47 beginning at line 17, at page 48 beginning at line 5, at page 51 beginning at line 17, at page 52 beginning at line 25, and also at page 53 beginning at line 4, the use of 1,000,000 ( $1 \times 10^6$ ) sperm is explicitly mentioned. Accordingly, support for the claimed ranges is found in the specification as one skilled in the art can appreciate.

Of note, the language, "at least some" was eliminated from claims 38, 40, 41, 43, 44, and 60-64 in the last response dated February 28, 2005. Accordingly, applicant believes that the examiner's concerns to the "at least some" language in claims 63 and 64 are moot.

Claims 63 mentions the aspect of equilibrating for period of about 1 hour to about 18 hours. This aspect is discussed in the specification on page 17 beginning at line 6. Further, claim 64 mentions the aspect of equilibrating for a period of not greater than 6 hours. This

aspect is found in the specification on page 17 lines 7-8. Accordingly, these claimed time limits are supported by the specification as one skilled in the art can appreciate. Further, the action suggests that the steps of claims 63 and 64 be clarified as performed between steps d) and e) of claim 38. Applicant believes this is clear since both claims 63 and 64 now include, *inter alia*, “equilibrating ... *prior to said freezing step ...*” (emphasis added).

In addition, claims 63 and 64 mention equilibrating sex-selected sperm cells to a cooler, non-freezing temperature. It may be desirable to cool the temperature of the sperm cells suspended in an extender to any temperature above freezing. As a non-limiting example, sperm can be cooled to 5 degrees Celsius. Of course, other temperatures may be used as one skilled in the art can appreciate.

#### 35 U.S.C. § 103 Concerns

The action expressed concerns to the claims under 35 U.S.C. § 103. A *prima facie* case of obviousness requires that the combination of references disclose all of the limitations of the claimed invention. As the claims are currently stated, the prior art does not include all of the elements nor limitations of independent claim 38.

To respond to the action’s questions, Table 1 of the specification shows (log) linear relationships for incubation times of 24 hours and 48 hours at different dilutions. Percentages of motile sperm increased as sperm concentration increased to  $10 \times 10^6$ / ml, (more consistently between  $5 \times 10^6$ / ml and  $10 \times 10^6$ / ml) but there was little difference thereafter as seen in Table 1.

As previously noted, the Spaulding reference proposes the use of antibodies as a vaccine or to achieve sex selection. Besides the fact that this reference has apparently not been shown to actually be achievable – and for convenience only -- the claims are at this stage distinguished from the Spaulding reference through their inclusion of the element of sorting the sperm cells without the presence of protective compounds in seminal plasma and suspending at dilutions of at least about 5 million per milliliter of extender to at least about 10 million per milliliter of extender. This technique is not mentioned in the Spaulding reference at the dilutions now set

forth. Further, in using this technique, the sperm are stripped of their natural protective compounds and thus are subjected to a more stressful environment. This aspect is not present when using the antibody approach of the Spaulding reference whether it be the immunization of the female (as proposed in Spaulding at column 4, line 43) or for example when binding monoclonal and polyclonal antibodies for sex-enriched semen samples (as proposed in Spaulding at column 4, line 50). Thus, the reference does not address the aspects claims and the section 103 concerns are not believed appropriate.

The Applicant believes all concerns raised in the May 13, 2005 office action have been addressed as best understood and that claims 38, 39, 42-54, 57-59, 63 and 64 remain in the case. Reconsideration and allowance of these remaining claims is respectfully requested at the Examiner's earliest convenience. Finally, should the Examiner have any remaining questions or disagree with any of Applicant's explanations, it is requested that the Examiner contact the undersigned by telephone in order to expedite the processing of this application.

Dated this 14 day of November, 2005.

Respectfully submitted,  
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